IN THE INTERNATIONAL BUREAU OF WIPO

In re PCT application of ELI LILLY AND COMPANY,) Authorized Officer:) Catherine Humbert
et al.))
International Application)
Number PCT/US00/16140) Mailing Date
) 24 January 2001
International Filing Date)
12 June 2000) Agent's File
) Reference:
Title of Invention) 7040339LLY54
PHARMACEUTICAL MATERIALS AND)
METHODS FOR THEIR PREPARATION	1)
ANDUSE	\

RESPONSE TO THE INTERNATIONAL SEARCH REPORT

The International Bureau **WIPO** 34, chemin des Colombettes 1211 Geneva 20 Switzerland

Dear Sir/Madam:

In response to the International Search Report mailed 13 December 2000, regarding the above-referenced PCT Patent Application, Applicant does not wish to make any amendments at this time.

Respectfully submitted

Thomas Q. HENRY, #28,509

Woodard, Emhardt, Naughton,

Moriarty & McNett

Bank One Center/Tower, Suite 3700

111 Monument Circle

Indianapolis, Indiana 46204 US

United States of America

(317) 634-3456

C10/018043

JC07 Rec'd PCT/PTO 1 0 DEC 2001

IN THE EUROPEAN PATENT OFFICE

In re PCT application of ELI LILLY AND COMPANY, et al.) Authorized Officer:) M Uhl)
)
International Application)
Number PCT/US00/16140	Mailing Date
) 25 July 2001
International Filing Date)
12 June 2000) Agent's File
) Reference:
Title of Invention	7040339LLY54
PHARMACEUTICAL MATERIALS AND)
METHODS FOR THEIR PREPARATION) .
AND USE)

RESPONSE TO WRITTEN OPINION OF THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

The International Preliminary Examining Authority European Patent Office Erhardstrasse 27 D-80298 Munich Germany

Dear Sir:

In response to the Written Opinion from the International Preliminary Examining Authority mailed 01 June 2001, Applicant does not wish to make any amendments.

Respectfully submitted

Thomas Q. HENRY, #28,309

Woodard, Emhardt, Naughton,

Moriarty & McNett

Bank One Center/Tower, Suite 3700

111 Monument Circle

Indianapolis, Indiana 46204 US

United States of America

(317) 634-3456

	(
	DATE. 12 June 2000
PCT INTERNATIONAL APPLICATION TRANSMITTAL LETTER	DOCKET OR REFERENCE NUMBER
REGARDING THE INTERNATIONAL APPLICATION OF ELI LILLY AND COMPANY, et al.	7040339LLY54
ENTIFICED PHARMACEUTICAL MATERIALS AND METHODS FOR THEIR	PREPARATION AND USE
Certification under 37 CFR 1.10	(if applicable) 12 June 2000
EL016471679US	
"Express Mail" mailing number	Date of Deposit
I hereby certify that this application is being deposited with the United Addressee" service under 37 CFR 1.10 on the date indicated above and Trademarks, Washington, D.C. 20231.	
LINDA S.W. CONPAS	Sinda S. W. Conrol
(Typed or printed name of person mailing application)	(Signature of person mailing application)
To the United States Receiving Office (RO/US): Accompanying this transmittal letter is the above-identified Ir Request form (PCT/RO/101). Please process the application account of Treaty.	nternational application, including a completed cording to the provisions of the Patent Cooper-
The following requests are made of the RO/US: 1. XX PREPARATION AND TRANSMITTAL OF CERTIFIED prepare and transmit to the International Bureau a cert documents identified in Box VI of the Request form (37 C)	FR 1.451).
To cover the cost of copy preparation and certification (37) KX a (check) (money order) in the amount of 8 15.00	included is attached to this transmittal letter.
The BOA'S is berein authorized to charge the following	deposit account no.:
2. XX CHOICE OF INTERNATIONAL SEARCHING AUTH Search be performed by the following International Search	HORITY—It is requested that the International inner Authority:
United States Patent and Trademark Office (ISA/US	5)
European Patent Office (ISA/EP)	Sheet Calculation Sheet
The appropriate Search fee for the above-named Auth (PCT/RO/101 Annex).	
3. SUPPLEMENTAL SEARCH FEES (ONLY WHEN SEARCH.)—Please charge any Supplemental Search International Searching Authority (ISA/US) to deposit ac	count no.:
 Judicedama that you continue; it any compact to my neal compensation thereof it contest against provincial or the Superior montal Sourch food, but is morely an ade 	n each instance and that it in no day round ministrative aid to assure that the ISA/US may timely complete
NOTE: SUPPLEMENTAL SEARCH FEES FOR ISA/EP ARE PATENT OFFICE	
4. XX DISCLOSURE INFORMATION—In order to assist in cation for purposes of determining whether a license to and for other purposes, the following information is supply	lied: *
A. There is no prior filed application relating to this	s invention.
	5 invention. 0/138,912 filed on 11 June 1999 (11.06.9
1. substantially identical to that of the acc	International application. The additional page
matter of the International application ap	ternational application.
C. Disclosure information cannot be covered by to involvement of several prior applications	the language of Points 4A or 4B above due to the or for other reasons. A separate sheet on is attached to this transmittal letter.
5. XX REQUEST FOR FOREIGN TRANSMITTAL LICE 184 and 37 CFR 5.11, a license to transmit the accompor international authorities is hereby requested.	and the first to the provisions of on color
SIGNER IS THE	
Thomas Q.	HENRY
OMMICH PEPPESENTATIVE	2
X . ATT. JANE 1. ALLENTI #29 300	Mad XXX

Sheet No. . ?.....

Agent's Ref: 7040339LLY54

Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)			
If none of the following sub-boxes is used, th	is sheet should not be it	ncluded in the request.	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.) CHMIELEWSKI, Jean A. 511 South 9th Street Lafayette, Indiana 47901 US		This person is: applicant only applicant and inventor inventor only (If this check-box is marked, do not fill in below.)	
State (that is, country) of nationality: US	State (that is, country) of	residence: US	
This person is applicant for the purposes of: X all designated the United States all designated the United States.		United States America only the States indicated in the Supplemental Box	
Name and address: (Family name followed by given name: for a ladesignation. The address must include postal code and name of cour address indicated in this Box is the applicant's State (that is, country) of residence is indicated below.) KAHR, Bart E. 4612 47th Avenue South Seattle, Washington 98118 US	egal entity, full official nory. The country of the of residence if no State	This person is: applicant only applicant and inventor inventor only (If this check-box is marked, do not fill in below.)	
State (that is, country) of nationality: US	State (that is, country) of	residence: US	
This person is applicant all designated for the purposes of:	States except the tes of America of A	United States America only the States indicated in the Supplemental Box	
Name and address: (Family name followed by given name; for a le designation. The address must include postal code and name of coun address indicated in this Box is the applicant's State (that is, country) of residence is indicated below.)	egal entity, full official by. The country of the office of residence if no State	This person is: applicant only applicant and inventor inventor only (If this check-box is marked, do not fill in below.)	
State (that is, country) of nationality:	State (that is, country) of	residence:	
This person is applicant all designated all designated for the purposes of:	States except the the confidence of America of	United States America only the States indicated in the Supplemental Box	
Name and address: (Family name followed by given name; for a le designation. The address must include postal code and name of coun address indicated in this Box is the applicant's State (that is, country) of residence is indicated below.)	itry. The country of the	This person is: applicant only applicant and inventor inventor only (If this check-box is marked, do not fill in below.)	
State (that is, country) of nationality:	State (that is, country) of	residence:	
This person is applicant all designated all designated States except for the purposes of: all designated all designated States except the United States of America only the Supplemental Box			
Further applicants and/or (further) inventors are indicated on another continuation sheet.			

DOX NO	DESIGNATION OF STATES			
1	lowing designations are hereby made under Rule 4.9(a)	mark the ap	oplicable check-boxes; at least one must be marked):	
_	al Patent		•	
	AP ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SL Sierra Leone, SZ Swaziland, TZ United Republic of Tanzania, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT MZ Mozama Angles			
⊠ EA	EA Eurasian Patent: AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT			
⊠ EP	DK Denmark, ES Spain, FI Finland, FR France, GB U	Jnited Kir	witzerland and Liechtenstein, CY Cyprus, DE Germany, ngdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, ther State which is a Contracting State of the European Patent	
⊠ OA	OAPI Patent: BF Burkina Faso, BJ Benin, CF Cent GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, other State which is a member State of OAPI and a Contr.	MR Maur acting Stat	n Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, ritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any te of the PCT (if other kind of protection or treatment desired,	
Nation	al Patent (if other kind of protection or treatment desired, spe	aifu on dat		
ı —	United Arab Emirates	_		
. —	Albania		Liberia	
		☑ LS	Lesotho	
	Armenia	🛛 LT	Lithuania	
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	Australia	🖸 LV	Latvia	
	Azerbaijan	MA MA	Morocco	
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☑ BG	Bulgaria		The former Yugoslav Republic of Macedonia	
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i —	Canada		Malawi	
_	and LI Switzerland and Liechtenstein		Mexico	
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⊠ CR	Costa Rica		•	
	Cuba	⊠ NZ	New Zealand	
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	Denmark	⊠ RO	Romania	
	Dominica	X RU	Russian Federation	
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	Grenada	☑ SL	Sierra Leone	
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	Gambia	TR	Turkey	
	Croatia	X TT	Trinidad and Tobago	
🔀 HU	Hungary	☑ TZ	United Republic of Tanzania	
⊠ ID	Indonesia	₩ UA	Ukraine	
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☑ IN	India	₩ us	United States of America	
IJ is	Iceland		·····	
☑ JP	Japan	☑ UZ	Uzbekistan	
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	Kyrgyzstan		Viet Nam	
⊠ KP		X YU	Yugoslavia	
	Democratic People's Republic of Korea	⊠ ZA	South Africa	
D1 1/5	D. 15. 66		Zimbabwe	
KR KR	Republic of Korea	Check-b	poxes reserved for designating States which have party to the PCT after issuance of this sheet:	
	Kazakhstan		Alacuia	
	Saint Lucia			
⊠ LK	Sri Lanka	AG AG	Antigua & Barbuda	
Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant				
at the expiration of that time limit. (Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)				



o. Agent's Ref: 7040339LLY54

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Supplemental Box If the Supplemental Box is not used, this sheet should not be included in the request.

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1. If, in any of the Boxes, the space is insufficient to furnish all the information: in such case, write "Continuation of Box No. ..." [indicate the number of the Box] and furnish the information in the same manner as required according to the captions of the Box in which the space was insufficient, in particular:

- (i) if more than two persons are involved as applicants and/or inventors and no "continuation sheet" is available: in such case, write "Continuation of Box No. III" and indicate for each additional person the same type of information as required in Box No. III. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residences indicated below:
- (ii) if, in Box No. II or in any of the sub-boxes of Box No. III, the indication "the States indicated in the Supplemental Box" is checked: in such case, write "Continuation of Box No. II" or "Continuation of Box No. II or "Continuation of Boxes No. II and No. III" (as the case may be), indicate the name of the applicant(s) involved and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is applicant;
- (iii) if, in Box No. II or in any of the sub-boxes of Box No. III, the inventor or the inventor/applicant is not inventor for the purposes of all designated States or for the purposes of the United States of America in such case, write "Continuation of Box No. II" or "Continuation of Box No. II" and No. III" (as the case may be), indicate the name of the inventor(s) and, next to (each) such name, the State(s) (and/or, where applicable, ARIPO, Eurasian, European or OAPI patent) for the purposes of which the named person is inventor;
- (iv) if, in addition to the agent(s) indicated in Box No. IV, there are further agents: in such case, write "Continuation of Box No. IV" and indicate for each further agent the same type of information as required in Box No. IV;
- (v) if, in Box No. V, the name of any State (or OAPI) is accompanied by the indication "patent of addition," or "certificate of addition," or if, in Box No. V, the name of the United States of America is accompanied by an indication "continuation" or "continuation-in-part": in such case, write "Continuation of Box No. V" and the name of each State involved (or OAPI), and after the name of each State (or OAPI), the number of the parent title or parent application and the date of grant of the parent title or filing of the parent application;
- (vi) if, in Box No. VI, there are more than three earlier applications whose priority is claimed: in such case, write "Continuation of Box No. VI" and indicate for each additional earlier application the same type of information as required in Box No. VI;
- (vii) if, in Box No. VI, the earlier application is an ARIPO application: in such case, write "Continuation of Box No. VI", specify the number of the item corresponding to that earlier application and indicate at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed.
- 2. If, with regard to the precautionary designation statement contained in Box No. V, the applicant wishes to exclude any State(s) from the scope of that statement: in such case, write "Designation(s) excluded from precautionary designation statement" and indicate the name or two-letter code of each State so excluded.
- 3. If the applicant claims, in respect of any designated Office, the benefits of provisions of the national law concerningnon-prejudicial disclosures or exceptions to lack of novelty: in such case, write "Statement concerning non-prejudicial disclosures or exceptions to lack of novelty" and furnish that statement below.

Continuation to Box No. IV Agent

WOODARD, Harold R.; EMHARDT, C. David; NAUGHTON, Joseph A., Jr.; MORIARTY, John V.; McNETT, John C.; HENRY, Thomas Q.; DURLACHER, James M.; REEVES, Charles R.; WAGNER, Vincent O.; ZLATOS, Steve; BEREVESKOS, Spiro; BAHRET, William F.; BROWNING, Clifford W.; FRISK, R. Randall; LUEDERS, Daniel J.; GANDY, Kenneth A.; THOMAS, Timothy N.; SISSELMAN, Kerry P.; JONES, Kurt N.; ALLIE, John H.; BANTA, Holiday W.; COLE, Troy J.; PAYNTER, L. Scott; LOWES, J. Andrew; MEYER, Charles J.; HARRIS, Darrin Wesley; SCHANTZ, Matthew R.; COY, Gregory B.; HIDAY, Lisa A.; DANILUCK, John V.; BROWN, Christopher A.; BRANNON, C. John; SCHWARTZ, Jason J.; USHER, Arthur J. IV; COLLIER, Douglas A.; MYERS, James B. Jr.; STEVENS, Scott J., and ROWE, James L., all of Woodard, Emhardt, Naughton, Moriarty & McNett, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, Indiana 46204 United States of America



Sheet No. .5.... Agent's Ref: 7040339LLY54

Box No. VI PRIORITY CI	LAIM	Further price	ority claims are indicated	in the Supplemental Box.	
Filing date	Number Where earlie		Where earlier applicat		
of earlier application (day/month/year)	of earlier application	national application: country	regional application:* regional Office	international application:	
item (1) (11.06.99)	60/138,912	us	·		
11 June 1999 item (2)					
Nem (2)			•		
item (3)					
The receiving Office is required of the earlier application(s) purposes of the present inte) (only if the earlier appl ernational application is	lication was filed with the the receiving Office) identifi	Office which for the ed above as item(s):	1)	
* Where the earlier application is a Convention for the Protection of Inc.	n ARIPO application, i t is n Iustrial Property for which t	nandatory to indicate in the Su hat earlier application was file	ipplemental Box at least or ed (Rule 4.10(b)(ii)). See Si	ne country party to the Paris upplemental Box.	
	NAL SEARCHING AU				
Choice of International Search (if two or more International Sear competent to carry out the interna the Authority chosen; the two-letter c	rching Authorities are sectional search, indicate	equest to use results of ear	requested from the Internal	tional Searching Authority):	
ISA / EP		ite (day/month/year) June 1999	Number (11.06.99) 60	Country (or regional Office) 0/138,912 US	
Box No. VIII CHECK LIST;	LANGUAGE OF FIL	ING			
This international application co	:	nal application is accompan	ied by the item(s) marke	ed below:	
· · · · · · · · · · · · · · · · · · ·	request : 5 1. \(\overline{\text{Y}}\) fee calculation sheet				
description (excluding sequence listing part) : 7	tion (excluding ce listing part): 70 2.				
claims :	3 4. 🔲 statemen	it explaining lack of signatu	ıre		
I	5. priority document(s) identified in Box No. VI as item(s):				
	6. translation of international application into (language):				
sequence listing part of description : n	7. separate indications concerning deposited microorganism or other biological material 8. nucleotide and/or amino acid sequence listing in computer readable form				
Total number of sheets: 81 9. other (specify): Transmittal Letter (dup)					
Figure of the drawings which should accompany the abstract: Language of filing of the international application: English					
Box No. IX SIGNATURE O	F APPLICANT OR AC	ENT			
Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).					
Applicant(s): ELI LILLY AND COMPAN	Y	Agent:	[]		
LEWIS, Jerry CHMIELEWSKI, Jean A.					
CHMIELEWSKI, Jean A. KAHR, Bart E.					
(Thomas Q. Henry)					
Date of actual receipt of the p international application:	For repurported	eceiving Office use only -		2. Drawings:	
3. Corrected date of actual receip	pt due to later but			received:	
timely received papers or drawings completing the purported international application:			_ <u></u>		
corrections under PCT Article	4. Date of timely receipt of the required corrections under PCT Article 11(2):			not received:	
5. International Searching Author (if two or more are competent	ority): ISA /		of search copy delayed fee is paid.		
		national Bureau use only			
Date of receipt of the record copy by the International Bureau:	у				
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D.C.T.	For re	eceiving Office use only	
PCT			
	International Application	No.	
REQUEST			
•	International Filing Date		
The undersigned requests that the present		•	
international application be processed according to the Patent Cooperation Treaty.	Name of receiving Office	and "PCT International Application"	
	Applicant's or agent's file reference (if desired) (12 characters maximum) 7040339LLY54		
Box No. I TITLE OF INVENTION	<u> </u>		
PHARMACEUTICAL MATERIALS AND METHODS FO	R THEIR PREPARAT	ION AND USE	
Box No. II APPLICANT			
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.) This person is also invertigated.		This person is also inventor.	
ELI LILLY AND COMPANY		Telephone No.	
Lilly Corporate Center Indianapolis, Indiana 46285 US		Facsimile No.	
		Teleprinter No.	
State (that is, country) of nationality: US	State (that is, country) of	residence: US	
This person is applicant for the purposes of: all designated		e United States America only the States indicated in the Supplemental Box	
Box No. III FURTHER APPLICANT(S) AND/OR (FURT	HER) INVENTOR(S)		
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.) This person is: applicant only			
LEWIS, Jerry 14104 Old Mill Circle		x applicant and inventor	
Carmel, Indiana 46032 US			
·	•	inventor only (If this check-box is marked, do not fill in below.)	
Characteristics and head of the	· ·		
State (that is, country) of nationality: US	State (that is, country) of	residence: US	
This person is applicant all designated all designate for the purposes of:		e United States	
X Further applicants and/or (further) inventors are indicated on a continuation sheet.			
Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE			
The person identified below is hereby/has been appointed to act of the applicant(s) before the competent International Authorities	on behalf X as:	gent common representative	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)			
HENRY, Thomas Q. WOODARD, EMHARDT, NAUGHTON, MORIARTY &	317-634-3456		
Bank One Center/Tower, Suite 3700	PENETI	Facsimile No.	

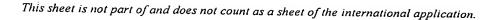
Indianapolis, Indiana 46204 US SEE CONTINUATION TO BOX NO. IV ON SHEET NO. 4

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Teleprinter No.



PCT For receiving Office use only FEE CALCULATION SHEET International application No. Annex to the Request Applicant's or agent's file reference 7040339LLY54 Date stamp of the receiving Office Applicant ELI LILLY AND COMPANY, et al. CALCULATION OF PRESCRIBED FEES 1. TRANSMITTAL FEE . . . 240 T 2. SEARCH FEE . S 990 International search to be carried out by (If two or more International Searching Authorities are competent in relation to the international application, indicate the name of the Authority which is chosen to carry out the international search.) 3. INTERNATIONAL FEE Basic Fee The international application contains 81 510 remaining sheets additional amount Add amounts entered at b1 and b2 and enter total at B . 937 Designation Fees The international application contains 86 designations. number of designation fees amount of designation fee payable (maximum 10) Add amounts entered at B and Dand enter total at I . I (Applicants from certain States are entitled to a reduction of 75% of the international fee. Where the applicant is (or all applicants are) so entitled, the total to be entered at I is 25% of the sum of the amounts entered at B and D.) 4. FEE FOR PRIORITY DOCUMENT (if applicable) 15 Р 5. TOTAL FEES PAYABLE . . 2918 Add amounts entered at T, S, I and P, and enter total in the TOTAL box TOTAL The designation fees are not paid at this time. MODE OF PAYMENT authorization to charge Х bank draft deposit account (see below) coupons cheque cash other (specify): postal money order revenue stamps DEPOSIT ACCOUNT AUTHORIZATION (this mode of payment may not be available at all receiving Offices) The RO/ US is hereby authorized to charge the total fees indicated above to my deposit account. (this check-box may be marked only if the conditions for deposit accounts of the receiving Office so permit) is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account. is hereby authorized to charge the fee for preparation and transmittal of the priority document to the International Bureau of WIPO to my deposit account. 23-3030 / work Deposit Account No. Date (day/month/year) Signature Thomas Q. HENRY #28,309